# Exhibit 1

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1993 WL 13139559 (E.D.Pa.)
**(Cite as: 1993 WL 13139559 (E.D.Pa.))**



**Motions, Pleadings and Filings**

Only the Westlaw citation is currently available.

United States District Court, E.D. Pennsylvania.
COCA-COLA BOTTLING COMPANY OF THE LEHIGH VALLEY, Plaintiff,
v.
Joseph F. GROL, Mark W. Kovacs, Peter J. Kearney, and Stefko Distributing
Company, Inc., d/b/a Caty Beverage Co., Defendants.
**Civ. A. No. 92-7061.**

March 8, 1993.

MEMORANDUM

HUYETT, District Judge.

*1 Plaintiff filed a complaint in this action on December 9, 1992 alleging violations of the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961 et seq. and various state law causes of action. The complaint essentially alleges that two of Plaintiff's former managers, Defendant Joseph F. Grol and Defendant Mark W. Kovacs, and two of Plaintiff's customers, Defendant Peter J. Kearney and Defendant Stefko Distributing Company, engaged in a pattern of racketeering activity through numerous schemes to siphon off Plaintiff's assets.

On December 23, 1992 Plaintiff served notices of depositions and subpoenas for documents on First Lehigh Bank, Northeastern Bank, Merchants Bank, Meridian Bank, American Travel Related Services, Inc., and First Valley Bank. Plaintiff made the document subpoenas returnable on February 1-3, 1993 and the subpoenas state that "no deponent need appear if records are produced on or before" the return dates of the subpoenas. Plaintiff also mailed copies of the notices of depositions and subpoenas to all Defendants. [FN1] On February 1, 1993 Defendant Kearney filed a motion for a protective order to quash the subpoenas or to stay discovery until the Court resolves Defendant Kearney's motion to dismiss Plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. Defendant Kearney raises five grounds in support of his motion, each of which the Court rejects, and therefore will deny Defendant Kearney's motion in its entirety.

Defendant Kearney claims that the notices of depositions are invalid because Plaintiff served them before Defendant Kearney was properly served with the complaint. Plaintiff served Defendant Kearney with the summons and complaint by mail pursuant to Federal Rule of Civil Procedure 4(c)(2)(C)(ii) on December 14, 1992. Because Plaintiff did not receive an acknowledgement of service within twenty days after the date of mailing, Plaintiff caused Defendant Kearney to be personally served on December 28, 1992. Any party may take the deposition of any person after the commencement of the action. Fed.R.Civ.P. 30(a). This action commenced on December 9, 1992 when Plaintiff filed the complaint. Fed.R.Civ.P. 3. The depositions were scheduled for February 1-3, 1993, well after the commencement of the action. Plaintiff did not need to obtain leave of the Court because the depositions were not scheduled "prior to the expiration of 30 days after service of the summons and complaint upon any defendant...." Fed.R.Civ.P. 30(a). The Rules authorized Plaintiff to compel nonparties to produce documents. Fed.R.Civ.P. 34(c). Plaintiff properly served Defendant Kearney with notice of the subpoenas on the nonparties by mail. *See* Fed.R.Civ.P. 45(b)(1), 5(b). The notices of depositions and subpoenas are not invalid. Finally, a party or person seeking a protective order has the burden of showing good cause. Fed.R.Civ.P. 26(c). Defendant Kearney has failed to show good cause because he has failed to show that he suffered any prejudice from the fact that Plaintiff served the notices of depositions before Defendant Kearney was served with the complaint.

*2 Defendant Kearney claims that the notices of depositions are invalid because Plaintiff served them before making the disclosures required under section 4:01(a) of the Civil Justice Expense and Delay Reduction Plan (Plan) adopted in this district. Defendant Kearney claims that the disclosures made by Plaintiff on January 18, 1993 were incomplete. According to the Plan, "a party may not seek discovery from any source before making the disclosures under subdivision (a)(1)...." Plan § 4:01(b). First, Plaintiff did not violate the Plan because Plaintiff made disclosures on January 18,

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1993, before the February 1, 1993 return date on the subpoenas. Second, Defendant fails to provide the Court with a copy of the disclosures provided by Plaintiff. Without seeing the disclosures, the Court will not rely on Defendant's conclusory allegation that the disclosure was "defective in that it gave no meaningful description of the documents, data, compilations and tangible things." Def.Mem. at 1. Third, Defendant Kearney has failed to show that he suffered any prejudice from Plaintiff's alleged noncompliance with section 4:01(a)(1).

Next, Defendant Kearney argues that the Court should stay discovery in this action because he has filed a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). A federal court has broad inherent power "to exercise appropriate control over the discovery process." *Herbert v. Lando*, 441 U.S. 153, 177 (1979). A court should not automatically stay discovery pending a motion to dismiss under Rule 12(b). Had the drafters of the Federal Rules of Civil Procedure wanted an automatic stay of discovery pending a motion to dismiss they could have so provided. *Moran v. Flaherty*, No. 92-3200, 1992 WL 276913 (S.D.N.Y. Sep. 25, 1992); *Gray v. First Winthrop Corp.*, 133 F.R.D. 39, 40 (N.D.Cal.1990). Rather, the decision whether to stay discovery pending a decision on a motion to dismiss is left to the sound discretion of the court. *Chrysler Capital Corp. v. Century Power Corp.*, 137 F.R.D. 209, 211 (S.D.N.Y.1991). Motions to stay discovery are not favored because when discovery is delayed or prolonged it can create case management problems which impede the court's responsibility to expedite discovery and cause unnecessary litigation expenses and problems. Requests to stay discovery are rarely appropriate where resolution of the motion to dismiss will not dispose of the entire case. In deciding whether to stay discovery pending a motion to dismiss a court must balance the harm produced by delay against the possibility that the motion will be granted and entirely eliminate the need for such discovery. *Simpson v. Specialty Retail Concepts, Inc.*, 121 F.R.D. 261, 263 (M.D.N.C.1988).

Where there is a motion to dismiss for failure to state a claim upon which relief can be granted, the court should take a preliminary look at the allegedly dispositive motion to see whether it is a challenge as a matter of law or to the sufficiency of the allegations. *See Hachette Distribution, Inc. v. Hudson County News Co.*, 136 F.R.D. 356, 358 (E.D.N.Y.1991). Where the motion merely addresses the sufficiency of the complaint, "resolution of the pending motion is not necessarily dispositive because the pleadings may be amended to correct the deficiencies." *Simpson v. Specialty Retail Concepts, Inc.*, 121 F.R.D. 261, 263 (M.D.N.C.1988).

*3 A preliminary look at Defendant Kearney's motion to dismiss reveals that, on the whole, Defendant Kearney challenges the sufficiency of the allegations of the complaint. Plaintiff's response to the motion to dismiss reveals that the dispute is over what a plaintiff must prove in a RICO action compared to what a plaintiff must plead in a complaint. In this situation, the motion may not be dispositive because even if granted, Plaintiff may be able to amend the complaint. In addition, the Court notes that the other defendants do not seek a stay of discovery nor have they made dispositive motions. Thus, even if the Court granted Defendant Kearney's motion, the action would continue. *See Hachette* 136 F.R.D. at 358-9. Moreover, Plaintiff seeks discovery from third parties, not Defendant Kearney, and the discovery sought is limited, not a "fishing expedition" as Defendant Kearney contends. Based upon all of these factors, then, a stay of discovery pending a decision on Defendant Kearney's motion to dismiss is unwarranted.

Defendant Kearney further states that he has been advised that the FBI is conducting an ongoing criminal investigation into the facts relating to "the Coca-Cola situation." Def.Mem. at 3. He argues that a stay of discovery is particularly appropriate where as here, a private litigant may be a "stalking horse" for government prosecutors who are using a civil action to circumvent the discovery limitations of criminal procedure. *Sharjah Inv. Co. (UK) Ltd. v. P.C. Telemart, Inc.*, 107 F.R.D. 81, 83 n. 2 (S.D.N.Y.1985). First, Defendant Kearney has failed to provide the Court with any evidence that the FBI is conducting a criminal investigation. Second, he has failed to show that the government is using Plaintiff's civil action to circumvent any limitations of criminal discovery.

Finally, Defendant Kearney argues that the deposition notices are "overly broad and inquire into matters which are not relevant, and are designed for the purpose of harassing, annoying, embarrassing, or oppressing the defendant." Def.Mem. at 3. A party moving for a protective order under Rule 26(c) must make a strong showing of "good cause" by demonstrating a particular need for protection. *Cippollone v. Ligget Group, Inc.*, 785 F.2d 1108,

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1121 (3d Cir.1986). First, Defendant Kearney has failed to provide the Court with copies of the notices of deposition at issue as required by Local Rule 24(b). Second, a party cannot rely on conclusory statements that the discovery is broad, not relevant, and harassing to show good cause under Rule 26(c). Defendant Kearney states that the depositions request the banks to produce documents relating to eleven persons and fail to provide account numbers. Plaintiff's discovery request is directed to third parties, not to Defendant Kearney. Defendant Kearney cannot realistically claim that he needs protection from these notices of depositions and subpoenas directed to the third parties. *See Howard v. Galesi*, 107 F.R.D. 348, 350 (S.D.N.Y.1985). Finally, Defendant Kearney has failed to show that the discovery will harass, annoy, oppress, or embarrass him.

***4** For the foregoing reasons, the Court will deny Defendant Kearney's motion in its entirety. An order follows.

ORDER

Upon consideration of Defendant Kearney's Motion for Protective Order to Quash Or At Least Stay Notices of Deposition For February 1, 1993, Plaintiff's response, and for the reasons stated in the foregoing memorandum, Defendant Kearney's motion is DENIED in its entirety.

IT IS SO ORDERED.

FN1. Neither the movant, Defendant Kearney, nor Plaintiff, has complied with Local Rule 24(b) which requires them to set forth verbatim the relevant parts of the notices and subpoenas at issue. The Court is relying on statements made in the motion and Plaintiff's response.

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# Exhibit 2

LEXSEE 2002 U.S. DIST. LEXIS 974

**IN RE CURRENCY CONVERSION FEE ANTITRUST LITIGATION**

**MDL No. 1409 M 21-95**

**UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK**

*2002 U.S. Dist. LEXIS 974; 2002-1 Trade Cas. (CCH) P73,563*

**January 22, 2002, Decided**
**January 22, 2002, Filed**

**DISPOSITION:** [*1] Defendants' motion to stay discovery pending resolution by this Court of their motion to dismiss denied in part and granted in part.

**LexisNexis(R) Headnotes**

**COUNSEL:** Dennis Stewart, Esq., Michael M. Buchman, Esq., Milberg Weiss Bershad Hynes & Lerach LLP, New York, New York, for Plaintiffs.

Merrill G. Davidoff, Esq., Berger & Montague, P.C., Philadelphia, Pennsylvania, for Plaintiffs.

Daniel B. Allanoff, Esq., Meredith Cohen Greenfogel & Skirnick, P.C., Philadelphia, Pennsylvania, for Waldman, Plaintiff.

Peter E. Greene, Esq., Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York, for J.P. Morgan Chase & Co., Chase Manhattan Bank USA, N.A., and The Chase Manhattan Bank, Defendants.

Jay N. Fastow, Esq., Bruce A. Colbath, Esq., Weil, Gotshal & Manges LLP, New York, New York, for MasterCard International Corp., Defendant.

Charles E. Buffon, Esq., Robert D. Wick, Esq., Covington & Burling, Washington, D.C., for Bank One Corp. and Fist USA Bank, N.A., Defendants.

M. Laurence Popofsky, Esq., Brian P. Brosnahan, Esq., Heller Ehrman White & McAuliffe LLP, San Francisco, California, for Visa U.S.A., Inc. and Visa International Service Association, Defendants.

Charles W. Douglas, [*2] Esq., David F. Graham, Esq., Sidley Austin Brown & Wood LLP, Chicago, Illinois, for Citigroup Inc., Citibank (South Dakota), N.A., Citibank (Nevada), N.A., Universal Financial Corp., Universal Bank, N.A., and Citicorp Diners Club, Inc., Defendants.

Alan S. Kaplinsky, Esq., Edward Rogers, Esq., Ballard, Spahr, Andrews & Ingersoll LLP, Philadelphia, Pennsylvania, for Providian Financial Corp., Providian National Bank Inc. and Providian Bank, Defendants.

Alexander Geiger, Esq., Geiger and Rothenberg, LLP, New York, New York, for Providian Financial Corp., Providian National Bank Inc. and Providian Bank, Defendants.

George A. Cummings, Jr., Esq., Kent M. Rogers, Esq., Brobeck, Phleger & Harrison LLP, San Francisco, California, for Household Credit Services, Inc., Defendant.

Mark P. Ladner, Esq., Morrison & Foerster LLP, New York, New York, for Bank of America Corp. and Bank of America N.A. (USA), Defendants.

**JUDGES:** WILLIAM H. PAULEY III, U.S.D.J.

**OPINIONBY:** WILLIAM H. PAULEY III

**OPINION:**

MEMORANDUM AND ORDER

WILLIAM H. PAULEY III, District Judge:

This action consolidates for centralized pretrial proceedings more than twenty putative class actions filed in this Court or [*3] transferred here by the Judicial Panel on Multidistrict Litigation ("JPML"). The underlying complaints challenge alleged foreign currency conversion policies at the two largest credit card networks, Visa and MasterCard, and their member banks, including Citigroup, Bank of America Corporation, Bank One Corporation, J.P. Morgan Chase & Company, Providian Financial Corp., and Household International, Inc. The complaints assert violations of the Sherman Act, *15 U.S.C. § 1* et seq., arising out of an alleged price-fixing conspiracy by and among Visa and Mastercard and their member banks, together with Diners Club, with respect to currency conversion fees. The complaints also assert claims under the Truth in Lending Act ("TILA"), *15 U.S.C. § 1601* et seq.

Presently before this Court is defendants' motion to stay discovery pending the resolution of their forthcoming motion to dismiss. For the reasons set forth below, defendants' motion to stay discovery is denied in part and granted in part.

District courts have discretion to stay discovery for "good cause" pending resolution of a motion to dismiss. See *Fed. R. Civ. P. 26(c)*; *Transunion Corp. v. Pepsico, Inc., 811 F.2d 127, 130 (2d Cir. 1987);* [*4] *Anti-Monopoly, Inc. v. Hasbro, Inc., 1996 U.S. Dist. LEXIS 2684, No. 94 Civ. 2120 (LMM) (AJP), 1996 WL 101277,* at *2 (S.D.N.Y. March 7, 1996). Good cause "requires a showing of facts militating in favor of the stay." *American Booksellers Ass'n v. Houghton Mifflin Co., 1995 U.S. Dist. LEXIS 2044, No. 94 Civ. 8566 (JFK), 1995 WL 72376,* at *1 (S.D.N.Y. Feb. 22, 1995). Courts in this District hold that a stay of discovery is appropriate pending resolution of a potentially dispositive motion where the motion "appear[s] to have substantial grounds" or, stated another way, "does not appear to be without foundation in law." *Chrysler Capital Corp. v. Century Power Corp., 137 F.R.D. 209, 209-10 (S.D.N.Y. 1991);* see also *Flores v. Southern Peru Copper Corp., 203 F.R.D. 92, 2001 WL 396422,* at *2 (S.D.N.Y. 2001) (power to stay initial disclosures "pending resolution of [a] motion to dismiss, if the defendant makes a strong showing that the plaintiff's claim is unmeritorious"); *Anti-Monopoly, 1996 U.S. Dist. LEXIS 2684, 1996 WL 101277,* at *2 (good cause "may be shown where a party has filed (or sought leave to file) a dispositive motion such as a motion to dismiss"). Still, imposition [*5] of a stay is not appropriate simply on the basis that a motion to dismiss has been filed, as the Federal Rules make no such provision. See *In re Chase Manhattan Corp. Sec. Litig., 1991 U.S. Dist. LEXIS 6136, No. 90 Civ. 6092 (LMM), 1991 WL 79432,* at *1 (S.D.N.Y. May 7, 1991).

Other factors courts consider in weighing whether to grant a stay of discovery include the breadth of discovery and the burden of responding to it, *Anti-Monopoly, 1996 U.S. Dist. LEXIS 2684, 1996 WL 101277,* at *3; *American Booksellers, 1995 U.S. Dist. LEXIS 2044, 1995 WL 72376,* at *1; *Chrysler Capital, 137 F.R.D. at 211,* as well as the unfair prejudice to the party opposing the stay, *Anti-Monopoly, 1996 U.S. Dist. LEXIS 2684, 1996 WL 101277,* at *3; *Chrysler Capital, 137 F.R.D. at 211.*

In urging a stay, defendants provide in only skeletal form the grounds on which they intend to move to dismiss. For the most part, defendants' description of their promised motion shows that they do not intend to challenge the antitrust or TILA claims on pure questions of law, but simply on the sufficiency of the facts alleged to support the claims. Thus, the type of motion defendants plan to interpose to the amended consolidated complaint [*6] does not militate in favor of a stay. See *Hachette Distrib., Inc. v. Hudson County News Co., 136 F.R.D. 356, 358 (E.D.N.Y. 1991)* (Spatt, J.) (factors relevant in stay application include whether "the issues before the Court are purely questions of law that are potentially dispositive"); 6 Moore's Federal Practice, § 26-105[3][c] (Matthew Bender 3d ed.) (factors relevant in stay application include "whether it is a challenge as a matter of law or to the sufficiency of the allegations").

Specifically, as to plaintiffs' principal claims asserted under the antitrust laws, defendants advert to the decision of District Judge Barbara S. Jones in *United States v. Visa U.S.A., Inc., 163 F. Supp. 2d 322 (S.D.N.Y. 2001),* where she rejected "dual governance" as a basis for a Section 1 claim. In her decision, Judge Jones held that the Government "failed to prove that the governance structures of the Visa and MasterCard associations have resulted in a significant adverse effect on competition or consumer welfare." *Visa, 163 F. Supp. 2d at 327.* Plaintiffs here, however, do not challenge dual governance itself, but charge that duality is [*7] a practice that facilitated the alleged conspiracy among defendants to fix currency conversion fees. As noted by Judge Jones, there was no claim in Visa "that member banks of Visa and MasterCard have conspired intra-association and inter-association to raise prices to consumers directly." *163 F. Supp. 2d at 330.* While the Visa decision may improve defendants' chances of success on a motion to dismiss with respect to the inter-association aspects of the charged antitrust conspiracy, defendants fall short of convincing this Court that they will be successful in dismissing the antitrust claims in their entirety at the pleading stage or, in any event, that the motion will be dispositive of all claims alleged.

In further support of their request for a stay, defendants point to the burdens attendant to proceeding

with discovery before the sufficiency of the amended consolidated complaint can be tested. Defendants' argument on this score is partially at odds with their prior conduct in the underlying actions. In cases pending in the Eastern District of Pennsylvania and this Court, defendants agreed to proceed with "first wave" discovery premised on the understanding **[*8]** that related cases would be transferred and consolidated by the JPML to a single district court for pretrial purposes. (See Ex. E to Decl. of Edward W. Millstein dated Oct. 23, 2001 ("Millstein Decl."): Second Case Management and Scheduling Order, Ross v. Visa U.S.A., Inc., No. 01-CV-1006 (E.D. Pa.) (the "Ross Order"); Ex. F. to Millstein Decl.: Proposed Case Management and Scheduling Order, Oshry v. Visa U.S.A., Inc., No. 01-CV-3610 (S.D.N.Y.).) For example, the Ross Order provided for the commencement of third-party document discovery, deadlines for responses to outstanding interrogatory and document requests propounded by plaintiffs, production of materials in a parallel California state action styled Schwartz v. Visa International Corp., and compliance with initial disclosure obligations pursuant to Rule 26(a). Having agreed to engage in "first wave" discovery with plaintiffs and having in fact begun to engage in such disclosures prior to the provisional stay entered by this Court (see Scheduling Order No. 1 dated Sept. 5, 2001), defendants offer no compelling reason why they should be able to disengage from those obligations now that consolidation has **[*9]** been effected.

Nevertheless, given the number of parties to this action and the substantial cost of discovery typical of antitrust cases of this magnitude, this Court in an exercise of its discretion concludes that a stay should be imposed on any non-custodial depositions until issue has been joined on plaintiffs' claims for relief. This Court notes that an amended consolidated complaint has yet to be filed and it would be wasteful to subject defendants' principals to wide-ranging depositions in the absence of a pleading that has withstood scrutiny under Rule 12(b)(6). See *Moore v. PaineWebber, Inc., 1997 U.S. Dist. LEXIS 203, No. 96 Civ. 6820 (JFK), 1997 WL 12805,* at *1 (S.D.N.Y. Jan. 14, 1997). The Visa decision provides a further reason for this measure because it may cabin the breadth of the conspiracy allegations in this case. Moreover, plaintiffs do not demonstrate any unfair prejudice owing to a stay of this kind, particularly in light of the degree of effort that will be required to manage document discovery alone in this case.

Accordingly, defendants' motion to stay discovery pending resolution by this Court of their motion to dismiss is denied in part and granted in part. To **[*10]** the extent they have not done so already, the parties shall comply with Rule 26(a)(1) initial disclosure requirements by March 1, 2002, or as they otherwise may agree. In addition, the parties are free to conduct document discovery and propound interrogatories as permitted by the Federal Rules and the Local Civil Rules of the Southern District of New York. A stay is imposed on any non-custodial depositions. Counsel for plaintiffs and defendants shall enter into a stipulation and order regarding the confidentiality of documents by February 11, 2002 and submit it to this Court for approval. As expressly contemplated by Section II of Pretrial Order No. 1 entered in this action, discovery in the coordinated action Waldman v. Citibank (South Dakota), N.A., 01 Civ. 8982 (WHP), shall be conducted in a manner consistent with the terms of this Order.

Dated: January 22, 2002

New York, New York

SO ORDERED:

WILLIAM H. PAULEY III

U.S.D.J.

# Exhibit 3

LEXSEE 2005 U.S. DIST. LEXIS 5127

**N.A.I.F. INC., Friend of Abdullah T. Hameen; ISMAA'EEL H. HACKETT; and SHAKIRAH HAMEEN, Plaintiffs, v. ROBERT SNYDER, BETTY BURRIS, LARRY MCGUIGAN, CHARLES CUNNINGHAM, RON G. HOSTERMEN, FRANK PENNELL, STANLEY W. TAYLOR, JR., CARL C. DANBERG, and PAUL HOWARD, Defendants.**

**Civil Action No. 03-506 JJF**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE**

*2005 U.S. Dist. LEXIS 5127*

**March 30, 2005, Decided**

**SUBSEQUENT HISTORY:** Summary judgment granted by *N.A.I.F. Inc. v. Snyder, 2005 U.S. Dist. LEXIS 5103 (D. Del., Mar. 30, 2005)*

**LexisNexis(R) Headnotes**

**COUNSEL:** [*1] For N.A.I.F., Inc., Plaintiff, Pro Se, Wilmington, Delaware.

For Ismaa'eel H. Hackett, Plaintiff, Pro Se, Wilmington, Delaware.

For Shakirah Hameen, Plaintiff, Pro Se, Philadelphia, Pennsylvania.

For Robert Snyder, Betty Burris, Larry McGuigan, Charles Cunningham, Ron G. Hostermen, Frank Pennell, Stanley w. Taylor, Jr., Carl C. Danberg, and Paul Howard, Defendants: Stuart B. Drowos, Esquire of the DEPARTMENT OF JUSTICE FOR THE STATE OF DELAWARE, Wilmington, Delaware.

**JUDGES:** Farnan, District Judge.

**OPINIONBY:** Joseph J. Farnan Jr.

**OPINION:**

**MEMORANDUM OPINION**

March 30, 2005
Wilmington, Delaware

**Farnan, District Judge**

Presently before the Court is the Motion To Reconsider The Court's Order Granting Plaintiff's Motion To Amend The Complaint (D.I. 27) filed by State Defendants Robert Snyder, Larry McGuigan, Betty Burris, Charles Cunningham, Ron Hosterman, Frank Pennell, Stan Taylor, Carl C. Danberg, and Paul Howard. For the reasons discussed, the motion will be denied.

**BACKGROUND**

Plaintiff Ismaa'eel Hackett is the Director and Iman of the North American Islamic Foundation, Inc. ("NAIF"), a national not-for-profit organization located in Wilmington, [*2] Delaware. Mr. Hackett and NAIF filed this lawsuit pursuant to *42 U.S.C. § 1983* as next friend of Abdullah T. Hameen, a former death row inmate who was executed in May 2001. Mr. Hackett volunteered his services as a religious advisor to Muslim inmates at the DCC. In their First Amended Complaint (D.I. 3), Plaintiffs Hackett and NAIF allege that Defendants violated Mr. Hameen's *First Amendment* right to freedom of religion when they failed to allow Mr. Hackett to act as Mr. Hameen's religious advisor at the time of his execution.

On October 24, 2003, Defendants filed a Motion For Summary Judgment (D.I. 14). On January 27, 2004, Plaintiffs Hackett and NAIF filed a Motion For Leave To File Second Amended Complaint (D.I. 23), in which they added Shakirah Hameen, Mr. Hameen's widow, as a plaintiff and added a claim pursuant to the Religious Land Use And Institutionalized Person Act ("RLUIPA"), *42 U.S.C. § 2000cc-1*. On February 9, 2004, the Court

entered an Order (D.I. 26) granting the Motion For Leave To File Second Amended Complaint. On February 23, 2004, Defendants filed the instant motion for reconsideration of the Court's February 9 [*3] Order.

**PARTIES' CONTENTIONS**

By their motion, Defendants contend that Plaintiffs' Motion For Leave To File Second Amended Complaint (D.I. 23) should be denied for three reasons: 1) Plaintiffs' motion is the product of undue delay; 2) Plaintiffs' amendment adding Ms. Hameen violates the applicable statute of limitations, and 3) the constitutionality of RLUIPA is questionable.

Plaintiffs respond that, because they are acting pro se, they did not have knowledge of RLUIPA at the times they filed the original Complaint and the First Amended Complaint. Plaintiffs further contend that RLUIPA is constitutional.

**LEGAL STANDARD**

"As a general rule, motions for reconsideration should be granted 'sparingly.'" *Stafford v. Noramco of Delaware, Inc., 2001 WL 65738* at *1 (D. Del. Jan. 10, 2001) (quoting *Karr v. Castle, 768 F.Supp. 1087, 1090 (D. Del. 1991))*. The purpose of granting motions for reconsideration is to correct manifest errors of law or fact, present newly discovered evidence, or to prevent manifest injustice. *Harsco Corp. v. Zlotnicky, 176 F.3d 669, 677 (3d Cir. 1999)* (citing *Keene Corp. v. Int'l Fid. Ins. Co., 561 F.Supp. 656, 665 (N.D. Ill. 1983)*; [*4] *North River Ins. Co. v. CIGNA Reins., 52 F.3d 1194, 1218 (3d Cir. 1995)* (citations omitted). Parties should remain mindful that a motion for reconsideration is not merely an opportunity to "accomplish [the] repetition of arguments that were or should have been presented to the court previously." *Karr v. Castle, 768 F. Supp. 1087, 1093 (D. Del. 1991)* (citing *Brambles U.S.A., Inc. v. Blocker, 735 F. Supp. 1239, 1240-41 (D. Del. 1990)*. However, a court should reconsider a prior decision if it overlooked facts or precedent that reasonably would have altered the result. Id. (citing *Weissman v. Fruchtman, 124 F.R.D. 559, 560 (S.D.N.Y. 1989))*.

**DISCUSSION**

For the reasons discussed, the Court concludes that State Defendants have not identified errors of law or fact, newly discovered evidence, or manifest injustice sufficient to allow the Court to grant the motion for reconsideration.

**I. Whether Plaintiffs' Motion For Leave To Amend Should Be Denied As The Product Of Undue Delay**

Defendants first contend that Plaintiffs' motion is the product of undue delay. Defendants specifically contend that Mr. Hackett [*5] possessed the information he added to his Second Amended Complaint at the time he filed his First Amended Complaint and, therefore, he acted in a dilatory manner. Defendants further contend that it was only after Mr. Hackett received Defendants' Motion For Summary Judgment (D.I. 27), wherein Defendants argued that Mr. Hackett lacked standing, that Mr. Hackett filed the Second Amended Complaint adding Shakeerah Hameen, Mr. Hameen's widow, as a plaintiff.

*Federal Rule of Civil Procedure 15(a)* declares that leave to amend "shall be freely given when justice so requires." *Fed. R. Civ. P. 15(a)*. In the absence of substantial or undue prejudice, denial of a motion for leave to amend a pleading "must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." *Lorenz v. CSX Corp., 1 F.3d 1406, 1414 (3d Cir. 1993)*.

The Court concludes that, although the amendment was made after Defendants filed a motion for summary judgment, Defendants have not shown they are substantially or [*6] unduly prejudiced by the amendment. The Court finds that Plaintiffs have not acted in bad faith or had dilatory motives in failing to add Ms. Hameen or file the RLUIPA claim in the original Complaint. Further, the Court finds no undue or unexplained delay on the Plaintiffs' part, particularly because they are acting pro se.

**II. Whether Plaintiffs' Motion For Leave To Amend Should Be Denied With Regard To Ms. Hameen On Statute Of Limitation Grounds**

Defendants contend that Plaintiffs' amendment adding Ms. Hameen should be denied on statute of limitation grounds.

The Supreme Court has held that the state statute of limitations for personal injury actions applies to *§ 1983* claims. See *Owens v. Okure, 488 U.S. 235, 239, 102 L. Ed. 2d 594, 109 S. Ct. 573 (1989)*; *Wilson v. Garcia, 471 U.S. 261, 269, 85 L. Ed. 2d 254, 105 S. Ct. 1938 (1985)*; *Smith v. City of Pittsburgh, 764 F.2d 188, 194 (3d Cir)*. In Delaware, the limitations period for a personal injury claim is two years. *Del. Code Ann. tit. 10, § 8119 (1974)*; *McDowell v. Delaware State Police, 88 F.3d 188, 190 (3d Cir. 1996)*.

*Federal Rule of Civil Procedure 15(c)* [*7] allows amendments that add a party despite the running of an applicable state statute of limitations in certain circumstances. *Fed. R. Civ P. 15(c)(3)*. To ameliorate the running of the statute of limitations, *Rule 15(c)(3)* imposes three conditions, all of which must be met for a party to successfully relate back an amended complaint

adding a new plaintiff. See *Singletary v. Pennsylvania Depot of Corrections, 266 F.3d 186, 193-94 (3d Cir. 2001)* (describing the three elements of *Rule 15(c)(3)*); see also *Nelson v. County of Allegheny, 60 F.3d 1010, 1014 n. 7 (3d Cir. 1995)*(noting that the relation back of amendments applies equally to amendments changing and adding plaintiffs). The three elements of *Rule 15(c)(3)* are whether 1) the claim arose out of the same conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading, 2) whether the defendant had notice of the filing of the action within the period provided by *Rule 4(m)* and will not be prejudiced in maintaining a defense, and 3) the newly named plaintiffs failed to add their names to the complaint because of a mistake. *Fed. R. Civ. P. 15(c)(3)* **[*8]** ; *Nelson, 60 F.3d at 1015.*

The Court finds that, in the circumstances of this case, Defendants had notice of and will not be prejudiced in maintaining a defense to the *§ 1983* claim. With respect to the third element, the Court finds that the facts in the instant case demonstrate that but for Mr. Hackett's mistake, Ms. Hameen would have been named in the Complaint. *Fed. R. Civ. P. 15(c)(3)(B).*

For these reasons, the Court concludes that under *Rule 15(c)(3)* Plaintiff's amendment adding Ms. Hameen as a plaintiff is entitled to relate back to the filing of the Complaint.

**III. Whether Plaintiffs' Motion For Leave To Amend Should Be Denied With Regard To The RLUIPA Claim**

Defendants contend that Plaintiffs' motion to amend adding a RLUIPA claim should be denied because the U.S. Supreme Court has yet to consider the constitutionality of RLUIPA.

*Federal Rule of Civil Procedure 15(c)(2)* allows an amendment stating a different claim than the original Complaint to relate back to the date of the original Complaint if the new claim is within the Court's jurisdiction and arises out of the **[*9]** conduct, transaction, or occurrence set forth in the original Complaint. *Fed. R. Civ. P. 15(c)(2).*

The Court concludes that the RLUIPA claim is within the Court's federal question jurisdiction and arises from the conduct set forth in the original Complaint. Thus, the Court concludes that Defendants' Motion To Reconsider (D.I. 27) should be denied with respect to the addition of the RLUIPA claim.

**CONCLUSION**

In sum, the Court concludes that State Defendants have not identified errors of law or fact, newly discovered evidence, or manifest injustice sufficient to allow the Court to grant the motion for reconsideration.

An appropriate Order will be entered.

**ORDER**

At Wilmington, this 30 day of March 2005, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the Motion To Reconsider The Court's Order Granting Plaintiff's Motion To Amend The Complaint (D.I. 27) filed by State Defendants is **DENIED.**

Joseph J. Farnan Jr.

UNITED STATES DISTRICT JUDGE

# Exhibit 4

LEXSEE 2002 U.S. DIST. LEXIS 24621

**In re PAXIL LITIGATION; THIS DOCUMENT RELATES TO ALL ACTIONS**

**CASE No. CV 01-07937 MRP**

**UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA**

*2002 U.S. Dist. LEXIS 24621*

**October 16, 2002, Decided**
**October 18, 2002, Filed; October 21, 2002, Entered**

**PRIOR HISTORY:** *In re Paxil Litig., 2002 U.S. Dist. LEXIS 16221* (C.D. Cal. Aug. 16, 2002).

**DISPOSITION:** [*1] Defendant's Motion for Reconsideration was granted and Plaintiffs' request for a preliminary injunction was denied.

**LexisNexis(R) Headnotes**

**COUNSEL:** For LESLI HAMILTON, KATHERINE KEITH, plaintiffs: Kevin J Yourman, Zev B Zysman, Weiss & Yourman, Los Angeles, CA. Karen Ann Barth, Baum Hedlund Aristei Guilford & Schiavo, Los Angeles, CA. Mary V Schiavo, Ohio State University, Columbus, OH. Donald J Farber, Donald J Farber Law Offices, San Rafael, CA.

For GLAXOSMITHKLINE, INC, defendant: Todd Davis, Andrew T Bayman, Chilton D Varner, King & Spalding, Atlanta, GA. Mark S Brown, King & Spalding, Washington, DC. David J Fleming, Drinker Biddle & Reath, Los Angeles, CA. Charles F Preuss, Thomas W Pulliam, Jr, Vernon I Zvoleff, Drinker Biddle & Reath, San Francisco, CA. Tamar P Halpern, Phillips Lytle Hitchcock Blaine & Huber, Buffalo, NY.

**JUDGES:** Honorable Mariana R. Pfaelzer, United States District Judge.

**OPINIONBY:** Mariana R. Pfaelzer

**OPINION: MEMORANDUM OF DECISION RE:**

Motion for Reconsideration of Order Granting Preliminary Injunction

## I. INTRODUCTION

On August 16, 2002, this Court entered an Order for Preliminary Injunction ("Order") in favor [*2] of Plaintiffs barring Defendant Glaxo Smithkline Beecham ("GSK") from continuing to air television commercials that make the claim that its prescription drug, Paxil, is "not habit forming."

In response, GSK filed a Motion to Suspend Preliminary Injunction Pending Appeal on August 19, 2002 and a Motion for Reconsideration on August 21, 2002. Additionally, at the Court's request, the United States Food and Drug Administration ("FDA") filed a supplemental brief on September 5, 2002. Oral argument by the parties and FDA was heard on October 8, 2002.

Having considered all the submitted papers as well as oral arguments, the Court GRANTS Defendant's Motion for Reconsideration and DENIES Plaintiffs' request for a preliminary injunction.

## II. DISCUSSION

GSK and FDA have advanced a multitude of arguments in support of the Motion for Reconsideration, some of which are essentially repetitions of those advanced in prior filings. The Court deems only three of the arguments raised as requiring further comment.

### A. Preemption

FDA and GSK assert that the Court's ability to pass judgment upon prescription drug direct to consumer advertisements is limited by the Supremacy Clause of [*3] the United States Constitution. The comprehensive nature of the Food, Drug, and Cosmetic Act ("FDCA"), *21 U.S.C. § 301* et seq., they argue, when taken together

with FDA's expertise, evidences a Congressional intent to preempt state law. Under their theory, control and regulation of these advertisements are within FDA's exclusive domain.

This argument is unpersuasive. To begin with, the parties reveal no case holding that the FDCA preempts state law either expressly or impliedly. If anything, FDA's and GSK's arguments run contrary to the grain of other decisions. See, e.g., *Knoll Pharm. Co. v. Sherman, 57 F. Supp. 2d 615 (N.D. Ill. 1999); Ohler v. Purdue Pharma. L.P., 2002 U.S. Dist. LEXIS 2368, 2002 WL 88945 (E.D. La. 2002); Motus v. Pfizer, 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000).*

Further, FDA's and GSK's position vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and GSK invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state **[*4]** claims. This position contravenes common sense, cf. *Medtronic, Inc. v. Lohr, 518 U.S. 470, 487, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996)*, and the Court declines the invitation.

**B. Primary Jurisdiction**

The Court also finds deferral under the doctrine of primary jurisdiction inappropriate. While FDA's expertise in areas such as drug efficacy and side effects cannot be lightly challenged, the Court has not found it necessary to delve into any of those areas. The preliminary injunction does not challenge FDA's finding that Paxil is not clinically addictive nor does it involve labeling, inserts, or material directed to prescribing physicians.

What it does challenge is FDA's and GSK's determination that the public is not likely to equate the words "not habit forming" as used in direct to consumer advertisements with "no withdrawal symptoms." The question of how members of the general public are likely to interpret (or misinterpret) a statement is within one of the courts' core competencies. Nothing here counsels otherwise.

**C. Likelihood of Success on the Merits**

While the Court is unwilling to blindly accept FDA's ultimate determination here, it **[*5]** has given careful consideration to the extensive fact-finding engaged in by FDA with regard to Paxil and its approval of Paxil's advertisements. Specifically, FDA has now presented evidence to the Court regarding not only the internal review process involved in the advertisements in question, but also its position that the advertisements are not misleading.

Once again, the Court reiterates that in resolving the question presented here, it is not required to decide, nor did it decide, whether Paxil is or is not habit forming. The Court is concerned only with whether in the specific direct to consumer advertisements before the Court, the statement that Paxil is not habit forming could be found to be misleading to consumers.

On this issue, the Court finds FDA's evidence persuasive such that it changes the Court's evaluation of Plaintiffs' likelihood of success on the merits to a degree dictating that the preliminary injunction be denied.

DATED: October 16, 2002

Honorable Mariana R. Pfaelzer

United States District Judge

# Exhibit 5

LEXSEE 1997 U.S. DIST. LEXIS 12560

**LAUREL K. SEATON, Plaintiff, v. KENNETH M. SEATON, Defendant.**

**NO. 3:96-CV-741**

**UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE, KNOXVILLE DIVISION**

*1997 U.S. Dist. LEXIS 12560*

**March 11, 1997, Filed**

**DISPOSITION:** [*1] Defendant's motion to compel [Doc. 6] DENIED.

**LexisNexis(R) Headnotes**

**COUNSEL:** For LAUREL K SEATON, plaintiff: Jerrold L Becker, John D Lockridge, Jr, Samuel W Brown, Lockridge, Becker & Valone, PC, Knoxville, TN. Melvin J Werner, Werner and Associates, Kingsport, TN.

For KENNETH M SEATON, FAMILY INNS OF AMERICA, INC., KMS ENTERPRISES, INC., WILLIAM HOWARD, defendants: Perry P Paine, Jr, Paine, Garrett & Bray, Maryville, TN.

**JUDGES:** Thomas W. Phillips, UNITED STATES MAGISTRATE JUDGE. Jarvis.

**OPINIONBY:** Thomas W. Phillips

**OPINION:**

**MEMORANDUM AND ORDER**

Pursuant to *28 U.S.C. § 636*(b) and the Rules of this Court, the Honorable James H. Jarvis has referred defendant's motion to compel [Doc. 6] to the undersigned for disposition or for a report and recommendation as may be appropriate [Doc. 9].

Defendant, Kenneth Marshall Seaton, has filed a motion to compel plaintiff, Laurel Knuckles Seaton, to answer defendant's first set of interrogatories and requests for production of documents and tangible things. Defendant asserts that plaintiff has filed suit alleging various causes of action, including violence against women, assault and battery, intentional infliction of emotional distress, false imprisonment, breach [*2] of fiduciary duty, fraud and conversion, and misrepresentation, for which she seeks damages from defendant, even though there has been pending between the same parties a divorce action in the Fourth Circuit Court for Knox County, Tennessee, styled *Laurel K. Seaton v. Kenneth M. Seaton,* Case No. 70086. This action was filed by plaintiff against defendant on August 23, 1995, almost one year to the day from the filing of the instant case in this court.

The only federal jurisdiction for this lawsuit in this court is alleged under *42 U.S.C. § 13981*(e)(3), the "Violence Against Women Act," *28 U.S.C. § 1331,* the "Federal Question" statute, with incorporated allegations under *28 U.S.C. § 1367,* dealing with supplemental jurisdiction.

Defendant points out that he has filed a motion to dismiss, or in the alternative, a motion for summary judgment, on the grounds that this court lacks jurisdiction over the subject matter and the person of defendant, the complaint fails to state a claim upon which relief can be granted, that the Violence Against Women Act is unconstitutional because it is beyond the powers of congress under Article I, section 8 (commerce clause), and section 5 of the [*3] Fourteenth Amendment (equal protection clause) of the Constitution of the United States. As to the supplemental claims, defendant asserts, plaintiff raises novel and complex issues of state law. The state law claims substantially predominate over the claim of Violence Against Women Act matters and involve other compelling reasons for declining jurisdiction in that the state law claims fail to state a claim upon which relief can be granted. Defendant further asserts that the matters involved in this

litigation are the subject of the prior divorce lawsuit and if they are not part of the state divorce proceedings, the applicable Tennessee statute of limitations would apply to bar the state claims (*T.C.A. § 28-3-104(a)*).

In conjunction with his motion to dismiss, or alternatively, for summary judgment, defendant served plaintiff with his first set of interrogatories and requests for production of documents and tangible things, which were to be answered within 30 days after service, and the documents and tangible things were to be produced for inspection and copying at the offices of counsel for defendant at 2:00 p.m. on November 12, 1996. Plaintiff did not answer the interrogatories **[*4]** nor did she or any representative for her appear at the designated time for the production of documents and tangible things. No request or contact from plaintiff was made to counsel for defendant to reschedule her compliance to answer the interrogatories or produce the documents and tangible things, defendant asserts, and counsel for defendant states that he has complied with *Rule 37(a)(2)(A), Federal Rules of Civil Procedure*, prior to the filing of this motion.

Defendant argues that the material sought in the first set of interrogatories and requests for production of documents and tangible things is all relevant to the issues of jurisdiction, as well as to liability, does not seek any privileged materials, and only seeks to discover matters that are properly discoverable under the Federal Rules of Civil Procedure. In addition, defendant asserts, the matters sought in the discovery relate to the preliminary motion filed by defendant to dismiss or, alternatively, for summary judgment, and thus, are proper matters for discovery at this time pursuant to E.D.TN.LR 26.1(c)(3).

Defendant asserts further that complete and truthful responses by plaintiff to the discovery sought by defendant **[*5]** will bear directly on the questions of jurisdiction and the application of the supplemental jurisdiction claim by plaintiff in the complaint and will help the court resolve the preliminary motion filed by defendant to dismiss and/or for summary judgment.

Counsel for defendant advised plaintiff's counsel by letter at the time of service of the first set of interrogatories and requests for production of documents and tangible things, that the discovery related to the preliminary motion to dismiss, or alternatively, for summary judgment already filed, at which time defendant counsel also proposed both counsel have the meeting required by *Rule 26(f), Federal Rules of Civil Procedure*, but received no response to his letter from plaintiff's counsel. Accordingly, defendant requests this court for entry of an order compelling plaintiff to truthfully, completely and fully answer the interrogatories propounded to her and to produce for inspection and copying the documents and tangible things sought in defendant's first set of interrogatories propounded to plaintiff and requests for production of documents and tangible things [Doc. 6].

Plaintiff has responded in opposition, pointing out that **[*6]** on August 22, 1996, plaintiff initiated this action by filing a complaint which alleges that (1) defendant violated the Violence Against Women Act (VAWA), *42 U.S.C. § 13981*, by engaging in felony crimes of violence against plaintiff motivated by gender and the defendant's perception of plaintiff's role as his wife, and (2) defendant also committed various state common law torts, including assault, intentional infliction of emotional distress, false imprisonment, fraud and conversion.

On September 10, 1996, defendant moved, pursuant to Rules 12(b) and 54(c) [sic], Federal Rules of Civil Procedure, for dismissal and/or summary judgment, on the grounds that the relevant statute, *42 U.S.C. § 13981*, was unconstitutional, as being ostensibly beyond the powers of congress under article I, section 8 (commerce clause) of the United States Constitution. The defendant filed essentially no brief in support of his position, plaintiff asserts, but did include and incorporate into his motion one opinion by the United States District Court for the Western District of Virginia in *Brzonkala v. Virginia Polytech and State University, 1996 WL 431097 (W.D. Va. 1996)*, which had found the VAWA **[*7]** unconstitutional. The defendant also moved to dismiss the pendent state law claims on the grounds that they predominated over the federal claim, and also moved for dismissal for failure to state a claim and for lack of personal jurisdiction. Defendant made no argument in support of the latter two grounds, plaintiff states, and in arguing for dismissal or summary judgment, defendant has relied exclusively on a lack of subject matter jurisdiction due to a purported constitutional infirmity in the VAWA.

On September 30, 1996, plaintiff filed her response to defendant's motion to dismiss/motion for summary judgment, which argues that this court does have subject matter jurisdiction to hear this cause, as the VAWA is constitutional. Plaintiff asserts that, in the interest of economy and simplicity of litigation, this court should rule upon defendant's motion to dismiss/motion for summary judgment, and the plaintiff's response thereto, prior to plaintiff having to respond to any discovery requests. The defendant has filed an expansive discovery request concerning each and every factual allegation of the complaint. Plaintiff asserts that none of the discovery is relevant to the threshold **[*8]** issue of this court's subject matter jurisdiction or the constitutionality of the VAWA. In addition, plaintiff asserts that although defendant does not appear actually to be relying on these

arguments, the information requested far exceeds anything necessary for determination of the personal jurisdiction issue raised by the defendant.

Plaintiff also asserts that there is currently a discovery dispute between the parties in regard to the pending state divorce case, *Seaton v. Seaton,* Knox County Fourth Circuit Court No. 73174. The discovery requests in this case, which are the subject matter of defendant's motion to compel, are much more relevant to the state divorce action, plaintiff argues.

Plaintiff points out that Local Rule 26.1(c) provides that:

> Unless otherwise stipulated in writing by the parties or ordered by the court in a particular case, formal discovery under *Fed. R. Civ. P. 30, 31, 33, 34,* and *36* may not be commenced before the meeting of the parties under *Fed. R. Civ. P. 26(f)* except in the following cases:
>
> (1) cases exempted under paragraph (d) of this rule from the requirement of a meeting of the parties;
>
> (2) cases. in which a temporary restraining **[*9]** order or preliminary injunction is sought; and
>
> (3) cases in which discovery is needed to resolve a preliminary motion such as an objection to personal jurisdiction or venue.

As of the date of the filing of this response, plaintiff asserts, the parties have not held a Rule 26(f) meeting, no formal discovery plan has been determined, and the parties are not subject to a scheduling order from this court. In addition, plaintiff argues that under E.D.TN.LR 26.1(c), no conditions exist which would provide for the commencement of discovery. The defendant has not seriously raised an issue over personal jurisdiction or venue in this case, plaintiff asserts, both parties reside in this district, and many of the allegations contained in the complaint arise in this district, as these incidents occurred while the parties were married and were living together as husband and wife. Defendant's initial position in this litigation has been to mount a facial challenge to the constitutionality of the VAWA, plaintiff asserts, and the discovery requested is irrelevant to this threshold issue. Thus, plaintiff concludes, this court should overrule defendant's motion to compel [Doc. 8].

A hearing **[*10]** was held on defendant's motion to compel on Monday, March 10, 1997, at the conclusion of which the court held a Rule 16(b) scheduling conference and set this matter for trial. A scheduling order has been prepared, and is being filed simultaneously with this memorandum and order. This case has now been set for trial on **August 21, 1997.**

Although this case has been filed in federal court, alleging a cause of action under a federal statute *(42 U.S.C. § 13981),* both parties have totally ignored the Federal Rules of Civil Procedure. *Rule 26(f), Federal Rules of Civil Procedure*, provides that except in cases exempted by local rule (and the instant case does not fall within this exception), the parties shall, as soon as practicable and in any event at least 14 days before a scheduling conference is held or a scheduling order is due under Rule 16(b), meet to discuss the nature and bases of their claims and defenses and the possibilities for a prompt settlement or resolution of the case, to make or arrange for the disclosures required by subdivision (a)(1), and to develop a proposed discovery plan. The attorney of record for all represented parties who have appeared in the case are **[*11]** jointly responsible for arranging and being present or represented at the meeting, for attempting in good faith to agree on the proposed discovery plan, and for submitting to the court within 10 days after the meeting a written report outlining the plan. The Rule 26(f) meeting has not been held, and neither side has requested the court to set the time and date for the Rule 26(f) meeting.

*Rule 26(a), Federal Rules of Civil Procedure*, is in full force and effect in the Eastern District of Tennessee. That rule, as well as Rule 26(f), is self-executing. That is, the court expects counsel for the parties to insure that the rules are followed. Both of these recent amendments to the Federal Rules of Civil Procedure were prompted in response to the Civil Justice Reform Act of 1990, and a major purpose of these provisions is to accelerate the exchange of basic information about the case and to eliminate the paperwork involved in requesting such information. The Advisory Committee Notes accompanying the 1993 amendments direct that the rule should be applied in a manner to achieve those objectives. Advisory Committee Notes, 1993 amendments. These measures were intended to minimize the cost and **[*12]** the delay incidental to federal litigation and to promote the basic purpose of the Federal Rules of Civil Procedure--the just, speedy, and inexpensive determination of every action. *Rule 1, Federal Rules of Civil Procedure.*

The instant cause of action was filed in this court on August 22, 1996 [Doc. 1]. Defendant filed a motion to dismiss or in the alternative, motion for summary judgment, on September 10, 1996 [Doc. 3]. On October

14, 1996, defendant served his first set of interrogatories and requests for production of documents and tangible things, and plaintiff's response thereto was due on or about November 12, 1996. However, both Rules 33 and 34 stipulate that, without leave of court or written stipulation, neither interrogatories to parties nor requests for production may be served before the time specified in Rule 26(d), *Federal Rules of Civil Procedure. Rule 26(d)*, Federal Rules of Civil Procedure, stipulates that except when authorized under the rules of civil procedure or by local rule, order, or agreement of the parties, a party may not seek discovery from any source before the parties have met and conferred as required by subdivision (f).

It is apparent, therefore, **[*13]** that the parties must first schedule and hold their Rule 26(f) meeting before pretrial discovery methods may be utilized. *Certain Underwriters at Lloyd's, et al v. Frichelle Ltd., 1996 WL 125957 (E.D. La. 1996).*

The reason for this requirement is, in large measure, because many of the matters sought in pretrial discovery procedures should be voluntarily provided by the parties as the result of the Rule 26(f) meeting. Rule 26(a)(1) requires the voluntary disclosure of the information and materials set forth in subparagraphs (A) through (D), and must be made within 10 days after the meeting of the parties under Rule 26(f).

A review of defendant's first set of interrogatories and requests for production of documents and tangible things, contrary to defendant's assertion, discloses that while the information requested appears to be relevant to the instant case, the requested information is not limited to information, documents, and tangible things related to defendant's motion to dismiss, or alternatively, for summary judgment. At the same time, there is no requirement under Rule 26(f), Rule 26(d), nor under *Rule 26(a), Federal Rules of Civil Procedure*, that the voluntary disclosure **[*14]** provisions of Rule 26(a) be restricted when a responding party files a dispositive motion under Rules 12 and/or *56, Federal Rules of Civil Procedure.*

Plaintiff has asserted that it is in the interest of economy and simplicity of litigation for this court to rule upon defendant's motion to dismiss/for summary judgment prior to plaintiff having to respond to any discovery requests. In other words, plaintiff is suggesting that the court stay discovery procedures pending resolution of defendant's dispositive motion. Such a suggestion is contrary to the clear letter and spirit of the newly enacted provisions of *Rule 26, Federal Rules of Civil Procedure*, and should not be permitted in this case.

A similar argument was presented to the United States District Court for the District of Massachusetts in the case of *In re Lotus Development Corp. Securities Litigation, 875 F. Supp. 48 (D. Mass. 1995)*, and the court ruled that to make a stay of discovery procedures more readily obtainable simply because there is a colorable motion to dismiss would undermine the spirit of the new rule. In that case, the parties did hold a Rule 26(f) meeting, a Rule 16(b) scheduling conference was held, and **[*15]** the defending party requested a stay of the automatic disclosure provisions of Rule 26(a)(1) because the defendants had filed a motion that the complaint be dismissed pursuant to *Rule 9(b), Federal Rules of Civil Procedure*, for failing to plead with specificity the alleged false and misleading public statements in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Proceeding with automatic disclosure and with pretrial discovery prior to the resolution of the pending motion, defendants argued, would impose on them unnecessary expense.

The district court rejected this position, however, because to do so would undermine the spirit of the new rule, and carve out a wholesale exception to automatic disclosure that is not specifically contemplated by the text or committee rules. *In re Lotus Development Corp. Securities Litigation, 875 F. Supp. at 51.*

This court agrees with the District Court for the District of Massachusetts that to stay automatic disclosure until a motion to dismiss is fully briefed and decided would undermine the spirit or Rule 26(a), and would carve out a wholesale exception to automatic disclosure that is not specifically contemplated **[*16]** by the text or committee notes. Plaintiff chose to file her cause of action in this court based upon alleged violations of the VAWA, *42 U.S.C. § 13981.* Plaintiff must have believed that she had a good cause of action under this statute or she would not have filed her cause of action. There should be no impediment, therefore, precluding plaintiff from fully complying with the voluntary and automatic disclosure provisions of *Rule 26(a)(1), Federal Rules of Civil Procedure.*

Accordingly, the parties are DIRECTED to hold their Rule 26(f) meeting within ten (10) days from the date of this memorandum and order. The parties are further DIRECTED to make the required disclosures at or within ten days of the Rule 26(f) meeting. The parties are further DIRECTED to develop a proposed discovery plan at the Rule 26(f) meeting which shall cover the parties' views and proposals concerning the items set forth in subparagraphs (1) through (4), and shall submit to the court within ten days after the meeting a written report outlining the required plan.

Defendant's motion to compel [Doc. 6] is DENIED at this time. Once the parties have developed a proposed discovery plan, and they have complied with **[*17]** the

voluntary and automatic disclosure provisions of Rule 26(a)(1), and if the information requested by defendant's first set of interrogatories and requests for productions of documents and tangible things are not provided voluntarily to defendant by plaintiff, defendant may then serve his first set of interrogatories propounded to plaintiff and requests for production of documents and tangible things upon plaintiff, and should plaintiff fail to timely respond thereto, defendant may renew his motion to compel at that time.

**IT IS SO ORDERED.**

**ENTER:**

Thomas W. Phillips

UNITED STATES MAGISTRATE JUDGE

# EXHIBIT 6

LEXSEE 1996 U.S. DIST. LEXIS 22567

**ZENITH LABORATORIES, INC., Plaintiff, v. ABBOTT LABORATORIES, Defendant.**

**Civil Action No. 96-1661**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

*1996 U.S. Dist. LEXIS 22567*

**August 5, 1996, Decided**
**August 7, 1996, Filed**

**NOTICE:** [*1] NOT FOR PUBLICATION

**DISPOSITION:** Defendant's motion to dismiss denied and plaintiff's motion for partial summary judgment denied.

**LexisNexis(R) Headnotes**

**COUNSEL:** For Plaintiff: William L. Mentlik, Esquire, Arnold H. Krumholz, Esquire, Roy H. Wepner, Esquire, Jeffrey S. Dickey, Esquire, LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, Westfield, New Jersey.

For Defendant: Anne M. Paterson, Esquire, RIKER, DANZIG, SCHERER, HYLAND & PERRETTI, Morristown, New Jersey.

For Defendant: Daniel E. Reidy, Esquire, James A. White, Esquire, Of Counsel, JONES, DAY, REAVIS & POGUE, Chicago, Illinois.

For Defendant: KENNETH D. GREISMAN, ESQUIRE, Of Counsel, Legal Division, Abbott Laboratories, Abbott Park, Illinois.

For Defendant: J. Daniel Kiser, Esquire, Of Counsel, FOX, BENNETT & TURNER, Washington, D.C.

**JUDGES:** JOHN W. BISSELL, United States District Judge.

**OPINIONBY:** JOHN W. BISSELL

**OPINION: BISSELL**, District Judge

This matter comes before the Court on a motion to dismiss and a motion for partial summary judgment. On April 15, 1996, plaintiff Zenith Laboratories, Inc. filed the instant complaint against defendant Abbott Laboratories. The complaint charges the defendant with unfair competition, abuse of process, [*2] tortious interference and fraud. It also seeks a declaratory judgment that plaintiff is not infringing defendant's relevant patents.

This Court has jurisdiction pursuant to *28 U.S.C. § 1331*.

**FACTS AND BACKGROUND**

The pharmaceutical industry is regulated by the Food and Drug Administration ("FDA"). The Federal Food, Drug and Cosmetic Act ("FFDCA") is the statute addressed to the manufacture and distribution of drugs and medical devices. See *21 U.S.C. § 301*, et seq. New drug products, methods for employing those products and variations of the original drug may all receive individual patents. Once a drug is patented, it must receive FDA approval before it may be marketed in the United States. (Id.) The FFDCA sets out the specific requirements for obtaining marketing approval by the FDA. (Id.) However, in 1984, the FFDCA was amended by the Drug Price Competition and Patent Term Restoration Act, otherwise known as the "Hatch-Waxman Act," which modifies the necessary approval procedures. (Codified as amended at *21 U.S.C. § 355* (1994) and *35 U.S.C. § 271*(d)-(h) (1995)). [*3]

The Hatch-Waxman Act provides for an abbreviated approval process for generic forms of previously approved pioneer drug products whose patents have or

will soon expire or are proven invalid. A pharmaceutical company seeking approval to market a generic product must complete an Abbreviated New Drug Application ("ANDA"). The generic producer is excused from conducting the extensive clinical tests required for a New Drug Application ("NDA"). The ANDA applicant may rely upon the pioneer company's tests. It need only prove that the generic contains the same active ingredient as, and is bioequivalent to, the patented drug.

Another significant difference made by the Hatch-Waxman Act is that the generic applicant may now use the patented drug to perform certain research and development without infringing the patent of the pioneer manufacturer. Prior to the amendment, the FFDCA provided:

> Whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Accordingly, prior to the Hatch-Waxman Act, a producer of a generic product was required to wait until the pioneer drug went off patent **[*4]** before that producer could conduct the research and development necessary for FDA approval of a generic product. As a result, the patent owner was entitled to a de facto extension of the term of the patent, the duration of which was equivalent to the time the generic producer needed to research its proposed product and obtain FDA approval. The FFDCA now reads:

> It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

*35 U.S.C. § 271*(e)(1). This provision is widely known as the "safe harbor" provision in that it permits otherwise infringing activity as long as it is reasonably related to obtaining regulatory approval for the generic drug product.

In the event the generic producer wishes to seek FDA approval during the term of the pioneer patent, the generic applicant must address each patent that claims the pioneer drug by including one of the following four certifications in its application:

> 1. that the pioneer has not filed patent information **[*5]** with the FDA,
>
> 2. that the patent has expired.
>
> 3. that the patent expires on a date before which the generic manufacturer is seeking to market its infringing equivalent, or
>
> 4. that the patent claiming the marketed pioneer drug is invalid or will not be infringed.

*21 U.S.C. § 355*(j)(2)(vii). If the generic applicant makes the fourth certification, it must provide notice of the certification to the patent owner and explain why the patent is invalid or will not be infringed. *21 U.S.C. § 355*(j)(2)(B). The Hatch-Waxman Act permits the patent owner to file a patent infringement action within 45 days of receipt of such notice. Prior to the Hatch-Waxman Act, preapproval patent infringement litigation was not available to the patent owner. The Act provides that infringement occurs if a generic manufacturer submits:

> an application under section 505(j) of the Federal Food, Drug and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.

*35 U.S.C. § 271*(e)(2). Such a suit delays the approval of the generic product **[*6]** up to 30 months or until a judicial resolution of the infringement issues, whichever comes first. *21 U.S.C. § 355*(j)(4)(B)(iii). Once a "paragraph IV" certification is made and an infringement action filed, the issues of the validity and accuracy of the patent are resolved by the court, not the FDA.

The Hatch-Waxman Act benefits only those patent owners whose patents have been approved by the FDA for marketing. For approval, a patent owner is required to:

> file with the FDA the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

*21 U.S.C. § 355*(b)(1). Once this information is received and the patent approved, it is published in a volume known as "Approved Drug Products With Therapeutic Equivalence Evaluations," which is commonly referred to as the "Orange Book." A patent is properly listed in the Orange Book if it claims an FDA-

approved [*7] drug product and is a patent with respect to which a claim of infringement could reasonably be asserted. Zenith argues that Abbott has improperly listed patents in the Orange Book by purporting that these patents claim the drug which is the subject of a pioneer patent with the purpose of invoking the Hatch-Waxman Act in order to keep Zenith out of the relevant market for up to 30 months and to subject it to sham patent infringement litigation.

Abbott discovered and patented terazosin hydrochloride, which is used for the treatment of hypertension and benign prostatic hyperplasia. The '894 patent covers the compound itself and the '097 patent covers a specific composition and the method for treating hypertension with terazosin hydrochloride. Both of these patents have expired. The '532 patent covers a dihydrate form of terazosin hydrochloride, which is marketed by Abbott as "Hytrin." The '532 patent expires in May 1998. At the time they were issued, the above patents were listed in the FDA Orange Book. Other patents issued to Abbott, which Abbott claims are covered by the '532 patent, include the '176 patent, the '617 patent, the '095 patent and the '207 patent. These patents are all [*8] for anhydrous polymorphs of terazosin hydrochloride and differ from Hytrin only in their specific crystalline forms. They are all bioequivalent to Hytrin. These patents were listed in the Orange Book in 1994 and 1995.

Zenith intends to market a polymorph of terazosin hydrochloride, which is bioequivalent to "Hytrin." Zenith claims that its product has a different crystalline structure and therefore does not infringe the patent on Hytrin. On or about August 1, 1994, Zenith filed an ANDA with the FDA seeking permission to market its generic version of an anhydrous form of terazosin hydrochloride. At the time, Zenith made the required certifications, including one with respect to the '894 patent, which had expired, one with respect to the '097 patent which would expire prior to the date Zenith sought approval, and one with respect to the '532 patent, alleging that Zenith's product would not infringe that patent. Abbott did not file a patent infringement suit in response.

However, Abbott contends that Zenith's product infringes not the '532 patent, but its '615 patent which covers an anhydrous polymorph of terazosin hydrochloride. In 1994, Abbott filed a patent infringement suit, pursuant [*9] to the Hatch-Waxman Act, asserting that Zenith was infringing the '615 patent. At the time, the '615 patent was not listed in the FDA Orange Book and the suit was therefore dismissed for failure to state a claim. Shortly thereafter, Abbott listed the '615 patent in the Orange Book, claiming that it covered Hytrin, the subject of Abbott's '532 patent, and refiled its complaint. However, that action was also dismissed, this time on the grounds that the listing was untimely. The issue of whether the '615 patent was improperly listed or infringed has not yet been addressed.

In its complaint, Zenith contends that Abbott's listing of the '615, '176, '095 and '207 patents was improper. Specifically, Zenith argues that none of these patents are covered by Hytrin, an approved drug product, as they claim. Because the listing of a patent entitles a patent owner to the protections of the Hatch-Waxman Act, Zenith claims that Abbott, knowing the relevant patents are not covered by Hytrin, had them listed anyway for the purpose of forcing Zenith to make a paragraph IV certification, which then entitles Abbott to have delayed FDA approval of Zenith's generic product for up to 30 months by instituting [*10] a patent infringement suit against Zenith. The complaint asserts counts of unfair competition, abuse of process, tortious interference and fraud. It also seeks a declaration that its generic product does not infringe any of Abbott's patents.

## ANALYSIS

### I. Abbott's Motion to Dismiss is Denied

A. Standard for a Motion to Dismiss

*Fed. R. Civ. P. 12(b)(6)* authorizes a court to dismiss a claim on the basis of a dispositive issue of law. *Neitzke v. Williams, 490 U.S. 319, 326, 104 L. Ed. 2d 338, 109 S. Ct. 1827 (1989)* (citing *Hishon v. King & Spalding, 467 U.S. 69, 73, 81 L. Ed. 2d 59, 104 S. Ct. 2229 (1984); Conley v. Gibson, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957)*. In disposing of a motion to dismiss, the court operates on the assumption that the factual allegations in the complaint or counterclaim are true. *Neitzke, 490 U.S. at 326-27*. A motion to dismiss may be granted if the opposing party would not be entitled to relief under any set of facts consistent with the allegations in the complaint or counterclaim. As the Supreme Court stated in Neitzke:

> nothing in [*11] Rule 12(b)(6) confines its sweep to claims of law which are obviously insupportable. On the contrary, if as a matter of law "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations," *Hishon, supra at 73, 104 S. Ct. 2229*, a claim must be dismissed, without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one. What Rule 23(b)(6) does not countenance are

> dismissals based on a judge's disbelief of a complaint's factual allegations.

*(490 U.S. at 327).*

**B. Zenith's Claims Arising Under State Law are not Preempted by the FFDCA.**

Zenith's complaint charges Abbott with state law claims of unfair competition, abuse of process, tortious interference with prospective economic advantage and fraud. It also seeks a declaration of noninfringement. The conduct from which these claims arose is the alleged improper listing of Abbott's patents in the FDA Orange Book which, as Zenith claims, precipitated sham patent infringement litigation. Abbott contends these claims are preempted by the FFDCA and moves to dismiss the action.

Certain claims are expressly **[*12]** preempted by the FFDCA. However, the parties agree that the state law claims at issue are not among those expressly preempted. In the absence of an express statutory provision, state law is preempted only when the state law "actually conflicts with federal law" or "federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 523, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992).*

As an initial matter, it is persuasive that Congress expressly preempted state law claims pertaining to the safety of medical devices but did not expressly preempt any other claims. *21 U.S.C. § 360k*(a). Such limited preemption leads to a reasonable inference that Congress intended to preempt only those claims specifically enumerated within the statute and for those not listed to remain viable. *Cipollone, 505 U.S. at 517.*

That the FFDCA is a comprehensive piece of legislation does not imply that it entirely occupies the regulated field.

> Preemption does not follow immediately from the comprehensive federal regulation **[*13]** of prescription biological products. Every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law.

*Abbot by Abbot v. American Cyanamid, 844 F.2d 1108, 1112 (4th Cir. 1988).* Furthermore, the state laws that regulate competition in the marketplace and the FFDCA are not in conflict and easily coexist. The goal of the FFDCA is the protection of public health. Common law claims such as those asserted here address wrongful business practices. It simply cannot be said that such state laws "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick, 514 U.S. 280, 115 S. Ct. 1483, 1487, 131 L. Ed. 2d 385 (1995).* In addition, state claims of unfair competition and the like provide a remedy for conduct not addressed by the FFDCA which is the alleged improper listing of patents with the FDA.

Numerous courts considering the issue of preemption of those state laws that regulate the conduct of competitors in the marketplace have found that **[*14]** state law claims similar to those asserted in the underlying complaint are not preempted. *Michael v. Shiley, Inc., 46 F.3d 1316, 1329 (3d Cir. 1995)* (common law fraud claim asserted against a competitor not preempted); *Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1029 (D.N.J. 1988)* (claims involving medical devices preempted, claims involving prescription drugs not preempted); *Hawkins v. Upjohn Co., 890 F. Supp. 609, 612 (E.D. Tex. 1994)* (fraud "and other general torts" not preempted by the FFDCA). Furthermore, a violation of the FFDCA that gives rise to a separate cause of action does not necessarily lead to the conclusion that such a claim is preempted. *Reese v. Payless Drug Stores Northwest, Inc., 34 Cal. App. 4th 19, 40 Cal. Rptr. 2d 75 (Ct. App. 1995)* (unfair competition not preempted). State law claims that do not hinge upon the validity or infringement of a patent are not preempted. *Cover v. Hydramatic Packing Co., 83 F.3d 1390 (Fed. Cir. 1996).* The instant state law claims involve the question of whether the defendant has attempted to invoke the provisions of the Hatch-Waxman Act to gain **[*15]** an unfair competitive advantage. For the reasons stated above, this Court concludes that the FFDCA does not preempt plaintiff's state law claims relating to alleged unlawful business practices.

**C. Zenith's State Law claims are Sufficient to Withstand a 12(b)(6) Motion.**

It must be remembered that on a motion to dismiss the complaint, "the plaintiff is afforded the safeguard of having all its allegations taken as true and all inferences favorable to plaintiff will be drawn." *Westinghouse Elec. Corp. v. Franklin, 789 F. Supp. 1313, 1317 (D.N.J. 1992)* rev'd on other grounds, *993 F.2d 349 (3d Cir. 1993).* A claim of unfair competition is one directed toward an entity that does not play fair, one who disparages or wrongfully captures the trade of another. *American Shops, Inc. v. American Fashion Shops of*

*Journal Square, Inc., 13 N.J. Super. 416, 420-21, 80 A.2d 575 (App. Div. 1951).* Unfair competition encompasses an actionable infringement of a property right, "i.e., the right to pursue one's business, calling or occupation free from undue interference or molestation." *Kamm v. Flink, 113 N.J.L. 582, 586, 175 A. 62* **[*16]** (E. & A. 1934).

In Count One, Zenith claims that Abbott has unfairly and unlawfully sought to obstruct competition in the market for terazosin hydrochloride by causing allegedly improper listings in the FDA Orange Book and instituting sham litigations against Zenith. New Jersey law provides:

> If a competitor . . . engages in fraud . . . or misrepresents, or threatens civil . . . actions, or violates the law, then the competition is considered to be outside of permissible parameters, and liability will ensue.

*C.R. Bard v. Wordtronics Corp., 235 N.J. Super. 168, 174, 561 A.2d 694 (Law Div. 1989).* Assuming the allegations in the complaint are true and considering that federal law does not preempt this claim, this Court determines that Zenith has articulated a claim of unfair competition against Abbott. n1 However, whether Zenith will ultimately prevail on such a claim is, at this time, far from clear.

> n1 This Court notes that Abbott's contention that the claim of unfair competition should be dismissed on the grounds that Zenith has not suffered any injury is unfounded. In the event that Abbott's conduct is ultimately determined to constitute unfair competition, Zenith has already had to defend against two "bogus" lawsuits for patent infringement. That money damages are not yet quantifiable is irrelevant.

**[*17]**

2. Abuse of Process

In Count Two, Zenith claims that the two prior lawsuits initiated by Abbott for patent infringement were improper and therefore an abuse of process. To prevail on a claim for abuse of process, the plaintiff must demonstrate an existence of an ulterior motive or purpose and some act in the use of legal process not proper in the regular prosecution of the proceedings. *Harris Custom Builders, Inc. v. Hoffmeyer, 834 F. Supp. 256, 263 (N.D. Ill. 1993).* Zenith claims that Abbott has filed patent infringement actions against it, knowing that those actions were meritless and with the purpose of attempting to keep Zenith out of the terazosin hydrochloride market for 30 months when Abbott knew it was not entitled to such an extension on its exclusive position in the pharmaceutical industry. Like Zenith's claim for unfair competition, the claim for abuse of process claim is sufficiently stated to withstand a motion to dismiss.

3. Tortious Interference with Prospective Economic Advantage

Count Three charges Abbott with tortious interference with Zenith's prospective economic advantage. The claimed economic advantage is that which Zenith expected **[*18]** to gain from the approval and marketing of its generic product. To prevail on such a claim, Zenith must establish that it had a reasonable expectation of economic benefit and that the defendant knowingly interfered with a benefit that had a reasonable likelihood of accruing to the plaintiff. *Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 186 (3d Cir. 1992).* The complaint charges Abbott with the knowledge that its '615 patent was improperly listed and the meritless pursuit of a patent infringement action with the purpose of keeping Zenith out of the terazosin hydrochloride market. Had Abbott's patent not been improperly listed, assuming for the instant purposes that it was, Zenith's generic product had a reasonable likelihood of approval without the statutory 30 month waiting period. Accordingly, Zenith has stated a claim for tortious interference with prospective economic advantage.

4. Fraud

Count Four charges Abbott with common law fraud. In order to state such a claim, plaintiff must allege: (1) defendant made a material factual misrepresentation to plaintiff; (2) with the knowledge or belief of its falsity; (3) with the intention that plaintiff rely **[*19]** upon the representation; and (4) that plaintiff justifiably relied upon the misrepresentation to its detriment. *Agathos v. Starlite Motel, 977 F.2d 1500, 1508 (3d Cir. 1992).* The fraud alleged to have occurred is Abbott's representation that it would use the samples of Zenith's generic product submitted to it by Zenith for the sole purpose of characterizing and identifying the terazosin hydrochloride in the generic product. (Letter dated Sept. 15, 1994, Exh. A). Zenith argues that Abbott received the samples, knowing the product could not infringe its '532 patent, with the intent of using those samples for the separate purpose of subjecting the compound to x-ray diffraction tests, which purpose was vastly beyond the scope of what was necessary to determine whether the '532 patent was infringed. (Letter dated Sept. 22, 1994).

Even if these promises of Abbott are considered half-truths, New Jersey courts hold:

> A half-truth may be as misleading as a statement which is wholly false. A fraudulent misrepresentation may inhere in a statement which is truthful so far as it goes but which is materially misleading because of the failure to recite qualifying matters. **[*20]** The intentional concealment of material information is tantamount to an affirmative misrepresentation of the nonexistence of such information.

*Medivox Productions, Inc. v. Hoffmann-LaRoche, Inc., 107 N.J. Super. 47, 69-70, 256 A.2d 803 (Law Div. 1969).* Accordingly, this Court concludes that Zenith has adequately alleged a claim of common law fraud.

**C. Zenith has Adequately Pled a Claim for a Declaratory Judgment.**

Zenith's fifth count seeks a declaratory judgment that its generic form of terazosin hydrochloride does not infringe any of Abbott's relevant terazosin hydrochloride patents. Zenith also seeks a declaration that the '615, '176, '095 and '207 patents are improperly listed in the FDA Orange Book in that none of those patents are covered by Abbott's Hytrin product and an order requiring Abbott to delist those patents.

For this Court to assert jurisdiction over Zenith's declaratory judgment claim, Zenith must have a reasonable apprehension of suit and have made meaningful preparation to commit acts Abbott would likely contest as infringing of its patents. *DuPont Merck Pharmaceutical v. Bristol-Myers Squibb, 62 F.3d 1397, 1401 (Fed.Cir. 1995).* **[*21]** Both elements are satisfied. Zenith is in a position to begin marketing immediately its generic product after FDA approval. In addition, Abbott has twice filed patent infringement suits against Zenith with respect to its generic of terazosin hydrochloride and has also filed similar suits against other potential marketers of terazosin hydrochloride. (Rocco Del., PP 3, 8, 14). This history of litigation regarding alleged infringement of Abbott's terazosin hydrochloride patents is a clear indication that, should Zenith seek approval of its generic product and make a "paragraph IV" certification that Abbott's patent is invalid, Zenith will be sued by Abbott for patent infringement, which suit would delay the marketing of the generic product for up to 30 months. *DuPont, 62 F.3d at 1400-1401* (holding the fear of an infringement suit in response to a "paragraph IV" certification was within that required to establish jurisdiction over a claim for a declaratory judgment); *Infinitech, Inc. v. Vitrophage, Inc., 842 F. Supp. 332, 337-38 (N.D. Ill. 1994)* (public interest in the development and marketing of new medical products favors the adjudication of a declaratory **[*22]** judgment action prior to the expiration of a patent in the event the patent may be invalid and undeserving of a full term). As Zenith has demonstrated that a controversy exists and that a declaratory judgment of noninfringement would not conflict with the purposes of the statutory system, this Court concludes that it has jurisdiction over Zenith's claim for a declaratory judgment. This Court also concludes that, having met the requirements for a declaratory judgment, plaintiff has satisfied the necessary jurisdictional showing regardless of the fact that the FFDCA does not expressly provide for a private right of action. it is not an action under the FFDCA plaintiff seeks to pursue but under the Declaratory Judgment and All Writs Acts and state law. n2

> n2 In fact, the Northern District of Illinois, in considering other listings of Abbott in the FDA Orange Book, entertained a request for a declaratory judgment and, having found those listings to be improper, ordered Abbott to remove those listed patents from the Orange Book. *Abbott Lab. v. Geneva Pharms., 1996 U.S. Dist. LEXIS 9762,* Civ. No. 95 C 6657 (N.D. Ill. Apr. 9, 1996) (Mentlik Decl., Exh. 20).

**[*23]**

**II. Zenith's Motion for Partial Summary Judgment is Denied.**

A. Standard for a Motion for Summary Judgment

*Federal Rule of Civil Procedure 56(c)* provides that summary judgment should be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 56(c)*; see also *Chipollini v. Spencer Gifts, Inc., 814 F.2d 893, 896* (3d Cir.) (en banc), cert. dismissed, *483 U.S. 1052 (1987).* In deciding a motion for summary judgment, a court must view the facts in the light most favorable to the nonmoving party and must resolve any reasonable doubt as to the existence of a genuine issue of fact against the moving party. *Continental Insurance Co. v. Bodie, 682 F.2d 436, 438 (3d Cir. 1982).* The moving party has the burden of establishing that there exists no genuine issue of material fact. See *Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986).*

The Supreme Court has stated [*24] that, in applying the criteria for granting summary judgment,

> the judge must ask . . . not whether . . . the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented. The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the [non-movant] is entitled to a verdict. . . .

*Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).* A fact is "material" only if it will affect the outcome of a lawsuit under the applicable law, and a dispute over a material fact is "genuine" if the evidence is such that a reasonable fact finder could return a verdict for the nonmoving party. (Id.)

In order to survive a motion for summary judgment, an opposing party must present "more than a mere scintilla of evidence" in his favor. He "cannot simply reallege factually [*25] unsupported allegations contained in his pleadings." *Anderson v. Liberty Lobby, 477 U.S. 242, 251, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986);* see also *Maguire v. Hughes Aircraft Corp., 912 F.2d 67, 72 (3d Cir. 1990).* Only evidence that would be admissible at trial may be used to test a summary judgment motion. Evidence with a deficient foundation must be excluded from consideration. *Williams v. Borough of West Chester, PA, 891 F.2d 458, 466 (3d Cir. 1989);* see also *Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs, 982 F.2d 884, 890-91 (3d Cir. 1992).*

B. The Instant Case

Zenith moves for summary judgment on the issue of whether the listing of Abbott's '176, '615, '095 and '207 patents was improper, In the event this Court were to make such a finding, Zenith asks for the entry of an order directing Abbott to delist those patents. Zenith argues that those patents are improperly listed because, although they claim Hytrin, none of them is actually covered by the Hytrin patent. Abbott disputes this and contends that its patents are covered by Hytrin. As Hytrin covers a dihydrate form of terazosin [*26] hydrochloride and the subsequent patents were issued for different anhydrous polymorphs of terazosin hydrochloride, which for the FDA's purposes are allegedly the same, Abbott submits that the contested patents properly claim Hytrin and that the listing of those patents in the FDA Orange Book was correct.

Title *21 U.S.C. § 355* sets out the requirements for the listing of drug patents in the FDA Orange Book:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

*21 U.S.C. § 335*(b)(1). The following regulation has been implemented by the FDA to facilitate compliance with § 355:

> For patents that claim a drug substance or a drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, [*27] or that claim a drug substance that is a component of such a product.

*21 C.F.R. § 314.53(b).* A listed drug is that which is also defined as approved for safety and effectiveness under § 355(c). *21 U.S.C. § § 355*(j)(2)(A) and (6)(A)(ii). Accordingly, the FDA approves for listing only those patents covered by an approved drug product. Therefore, if Abbott's patents are covered by Hytrin, which is an approved drug product, listing is appropriate.

As an initial matter, the FDA approved Abbott's '176, '615, '095 and '207 patents for listing. Such approval demonstrates that the FDA believed that those patents are covered by an approved drug product. The drug product that the FDA agreed covered the contested patents is, as those patents claim and Abbott submits, Hytrin. Both parties cite Pfizer, Inc. v. FDA in support of their arguments. *753 F. Supp. 171 (D. Md. 1990).* In Pfizer, the FDA refused to list a patent that failed to claim an approved drug product. Specifically, Pfizer had an approved patent which claimed nifedipine solution in an oral release capsule. It then sought to have approved a patent on a tablet formulation of nifedipine. [*28] As the tablet patent did not claim the FDA-approved oral release capsule, the FDA refused to approve the tablet formulation of nifedipine. n3 However, the patents at

issue in the instant case do not claim an unapproved drug product, they claim the FDA-approved drug product of Hytrin.

> n3 Although not discussed in the papers, it would seem that the purpose behind the requirement that a patent for which approval is sought must claim an approved drug product is that it allows the FDA to rely on the testing results of the previously-approved drug product in approving the patent that is the subject of the second application. In other words, if a patent for which approval is sought claims an approved drug product, the later patent may be approved on a more expedited basis because the FDA can rely on the tests performed on the previously-approved patent. This is essential because, where the later patent claims an approved drug product, it is considered the bioequivalent of that product. If a patent for which approval is sought fails to claim an approved drug product, it would likely be required to submit to lengthy and stringent safety and efficacy tests.

**[*29]**

Zenith argues that, although the FDA found that the patents are covered by Hytrin, which must be undisputed as the FDA approved and listed each of the contested patents, this does not necessarily mean that the patents are actually covered by, or claim, Hytrin. n4 Hytrin and the four patents at issue all have different crystalline formulations. As such, Zenith contends that one anhydrous polymorph is not covered by a different anhydrous polymorph. If this argument is correct, one anhydrous polymorph would not be covered by a different yet FDA-approved, anhydrous polymorph, and could therefore not be listed without its own safety and efficacy testing.

> n4 The FDA admits that it does not have the resources to examine whether a patent is properly listed after listing takes place. If a listing is contested, the FDA requires the patent owner to certify that the listing is appropriate or to voluntarily cause the patent to be delisted. *21 C.F.R. § 314.53(f)*. Unless the patent owner changes the information submitted to the FDA, the FDA will not amend the Orange Book listing. (Id.) Abbott has certified that the listings are valid and refuses to delist its patents.

**[*30]**

The crux of this motion for partial summary judgment on the issue of improperly listed patents is what a subsequent patent must claim to be appropriate for listing. Must the patent claim only an approved drug product or must it claim both the approved drug product and, in the case of an anhydrous polymorph, its exact crystalline structure. Abbott argues that, because Hytrin, a dihydrate form of terazosin hydrochloride, is the drug product covered in the relevant patent, the subsequent patents need only claim the drug substance claimed in Hytrin. As the relevant patents were issued with respect to anhydrous polymorph of Hytrin, which differ only in crystalline structure, Abbott submits that they are covered by Hytrin.

The C.F.R. provides:

> For patents that claim a drug substance or a drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of an . . . approved application, or that claim a drug substance that is a component of such a product.

*21 C.F.R. § 314.53(b)*. This Court reads this section to mean that if a patent claims the drug substance, or active ingredient, of an approved drug product, **[*31]** that patent is covered by the approved drug product and may be approved for marketing by the FDA and listed in the Orange Book.

The issue then becomes what is the relevant drug substance claimed by Hytrin and do the later Abbott patents claim that substance so that listing would be appropriate. Zenith argues that the relevant drug substance is the specific dihydrate form of terazosin hydrochloride, which is an anhydrous polymorph of terazosin hydrochloride. It argues that other crystalline forms of terazosin hydrochloride Abbott has patented do not claim the specific polymorph found in Hytrin. However, Abbott contends that the relevant drug substance is a general hydrated form of terazosin hydrochloride, and not the specific dihydrate formulation of that drug. In other words, Abbott argues that any patent on an anhydrous polymorph is covered by Hytrin as Hytrin claims a hydrated form, of the active ingredient and not the chemical make-up of that formulation.

The FDA provides that "anhydrous and hydrated entities are considered pharmaceutical equivalents." (Orange Book at xii, Coleman Decl., Exh. B). Pharmaceutical equivalents contain the same active ingredient. (Id., at vii). **[*32]** They differ in "shape, scoring configuration, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling." (Id.) The FDA has

indicated that, as a general matter, "different polymorphic forms of the same drug substance (are the same) drug substances unless the differences in physical structure found in the polymorphs result in inequivalent safety and efficacy profiles." (FDA Response to Citizen Petition of Janssen Pharmaceuticals, Coleman Decl., Exh. C at 4). The FDA also considers "differences in waters of hydration resulting in polymorphic crystal forms of the same active moiety (i.e., different forms of the same active ingredient) to be the same when dissolution, solubility, and absorption are shown to be equivalent." (Letter from the Center for Drug Evaluation and Research, Coleman Decl., Exh. D at 4).

The contested patents are for different anhydrous polymorphs of terazosin hydrochloride. As stated above, different polymorphic forms containing the same active ingredient may be considered by the FDA as equivalents. However, this is the case only if the dissolution, solubility and absorption of the polymorphs are **[*33]** the same. It is not clear that these factors are consistent as between Hytrin and the later patents. Accordingly, a question of fact exists as to whether the later Abbott polymorphs are covered by Hytrin. There is simply not enough undisputed information before this Court for it to decide under the summary judgment standard whether a dihydrate version of terazosin hydrochloride covers anhydrous polymorphs that differ only in crystalline structure. In the event these polymorphs do have the same dissolution, solubility and absorption as that found within the drug substance in Hytrin, their patents would likely be construed as properly claiming the drug substance in Hytrin and the listing of those patents would be correct. However, if these polymorphs are found not to claim the drug substance in Hytrin, they could not likely claim to be covered by that drug substance and would then not be entitled to listing in the Orange Book. Those issues cannot presently be resolved summarily. Accordingly, Zenith's motion for partial summary judgment is denied.

**CONCLUSION**

For the foregoing reasons, defendant's motion to dismiss is denied, and plaintiff's motion for partial summary judgment **[*34]** is also denied.

JOHN W. BISSELL

United States District Judge

DATED: August 5, 1996

**ORDER**

For the reasons set forth in the Court's Opinion filed herewith,

It is on this 5th day of August, 1996

**ORDERED** that defendant's motion to dismiss plaintiff's complaint be, and it hereby is, denied; and it is further

**ORDERED** that plaintiff's motion for partial summary judgment be, and it hereby is, denied.

JOHN W. BISSELL

United States District Judge